IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Docket No.: 821405-1010

KWFI DAM, Adriaan Cornelis Art Unit: 1794

Serial No.: 10/502.108 Examiner: Bekker, Kelly J.

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For: Method for the Preparation of a Meat Substitute Product, Meat Substitute Product
Obtained with the Method and Ready to Consume Meat Substitute Product

REPLY BRIEF

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Sir:

This Reply Brief under 37 C.F.R. §41.41 is timely submitted in response to the Examiner's Answer mailed November 12, 2009 (also the "Answer") and in support of the Notice of Appeal filed April 3, 2009, appealing the Board from the Final Office Action, mailed December 3, 2008 (Paper No. Mail Date 20081124), finally rejecting claims 1, 2, 4-14 and 21-27 of the above-referenced application and in response to the Examiner's Answer mailed November 12, 2009. No new or non-admitted amendment or any new or non-admitted affidavit or other evidence is submitted with this Reply Brief.

(9) Grounds of Rejection

The only rejections presented are on the basis of obviousness under 35 U.S.C. §103(a) in view of the combination of Shenouda and Monsanto. As noted at page 4 of the Appeal Brief filed August 10, 2009, the Examiner has the burden to establish a <u>prima facie</u> case of obviousness by providing a rationale demonstrating that an objective teaching in the prior art or knowledge generally available would lead one of ordinary skill in that art to the claimed invention.

As shown below and in the Appeal Brief, the Examiner fails to meet this burden for establishing the rejections. The Examiner attempts to meet this burden by incorrectly interpreting the Shenouda and Monsanto references, and incorrectly combining the references contrary to their respective teachings. Further, as shown below and in the Appeal Brief, even if the Shenouda and Monsanto references are properly combinable in the manner suggested in the Examiner's Answer, their combination would not result in each and every feature recited in the pending claims, and thus their combination fails to render the claims obvious.

A. Shenouda

Applicant respectfully disagrees with the Examiner's interpretation of Shenouda presented in the Answer. According to the Examiner (Answer, page 4, lines 6-17 and page 10, lines 21-29) Shenouda teaches a method for the preparation of a ready to consume gelled protein product which is a meat substitute product, comprising:

- combining a milk protein (column 2, lines 50-68), alginate (column 3, lines 21-28) and water (column 2, lines 13-31);
- forming the combination into a homogeneous mixture (columns 2, lines 38-40 and column 3, lines 15-20)
- mixing the water protein alginate composition with a solution containing the gelling agent calcium chloride to form a fibrous product (column 7, lines 1-36); and

· isolating the fibrous product by heat setting to form independent fibers.

This interpretation of Shenouda is incomplete and incorrect. Further it fails to consider the full teachings of Shenouda. Shenouda, for example, does not teach mixing of a homogeneous mixture with a gelling agent containing solution to form a fibrous product, as recited in step (c) of pending claim 1. Instead, Shenouda teaches to produce fiber bundles by a freeze-slice-thaw (melt) treatment in which the fiber bundles produced by the slicing are infused with gelation ions during the thawing (melting) (claim 1, column 6, lines 37-48). See also, Appeal Brief, page 9.

Column 7, lines 1-36 of Shenouda, does not support the Examiner's interpretation.

Instead this citation relied on by the Examiner teaches a procedure in which a subdivided frozen mass of fiber bundles are immersed in an appropriate bath (e.g. a bath containing calcium salts) to gel the water-soluble alginate in each fiber bundle. In lines 7-8 it is stated "Gelling serves to reinforce the well-defined, well-ordered, fiber-like structure in each bundle". In other words, no fibrous product is formed during Shenouda's gelation of the alginate. In the process taught by Shenouda the fiber bundles have already acquired their fibrous structure before they are subjected to the alginate gelation step.

On page 11, lines 11-12, of the Examiner's Answer it is asserted that "the instantly claimed invention does not require that the actual fibers be formed by the metal cation". This is incorrect. Step (c) of the pending claims recites that a homogeneous mixture comprising protein material, alginate and water is mixed with a solution of a metal cation with a valency of at least 2, in order to form a fibrous product. Thus, the formation of the fibrous product is intrinsically linked to the mixing of the homogeneous mixture with the multivalent cation solution.

B. Monsanto

Furthermore, Applicant strongly disagrees with the interpretation of Monsanto in the Answer. On page 5, lines 10-11 of the Examiner's Answer it is stated: "Monsanto teaches of forming retort stable dairy protein gels (abstract and page 3 lines 1-4), which were known to be used as meat substitutes, as shown by Shenouda". This, too, is incorrect.

Instead Monsanto teaches gellan-based, heat-stable gel pieces that can suitably be added to beverages, retorted snacks, dessert toppings, puddings and retort stable protein gels (page 2, lines 27 ff.). Thus, Monsanto does not contain any suggestion that the retort stable gel pieces described therein can be used as meat substitutes. Furthermore, Applicant cannot find any statement in Shenouda that could have suggested to a person of ordinary skill in the art that the gellan-based gel pieces of Monsanto could be used as meat substitutes.

C. The Lack of Incentive to combine Shenouda and Monsanto

The Examiner relies on certain arguments to support the rejections based on an incorrect and improper combination of Shenouda and Monsanto. There is no incentive to combine Shenouda and Monsanto in the manner suggested in the Answer.

According to the Examiner (Answer, page 5, end of 2nd par.), Monsanto teaches that polyphosphate is added to the hydrocolloid mixture before combining the hydrocolloid and protein so that the protein does not precipitate and to facilitate stability in the product (citing Monsanto: page 3, lines 32-35; page 5, lines 29-35 and page 6, lines 8-35).

The Examiner further argues as follows: Regarding the combined alginate, i.e. hydrocolloid, and protein mixture as formed in the presence of a calcium complex forming agent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sequestrant, i.e. a calcium complex forming agent, with the hydrocolloid or the protein as it was desirable to include non-coagulating agents in the protein/hydrocolloid mixture as taught by Shenouda and so that when combined the hydrocolloid would have

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reduced precipitation. i.e. coaqulation with the protein and a stable product would be formed, as taught by Monsanto.

Also elsewhere in the Examiner's Answer (see page 9, lines 20-23; page 10, lines 12-15) the Examiner has argued that:

A It would have been obvious to one of ordinary skill to include a sequestrant with the hydrocolloid or the protein as it was desirable to include non-coagulating agents in the protein/hydrocolloid mixture as taught by Shenouda

and/or

B. It would have been obvious to one of ordinary skill to include a sequestrant with the hydrocolloid or the protein so that a stable product would be formed, as taught by Monsanto.

The fallacy of these lines of argumentation in the Answer is separately shown below.

1. Contrary to the Answer it was not desirable to include non-coagulating agents in the protein/hydrocolloid mixture as taught by Shenouda

The Examiner supports the assertion that it would be desirable to include noncoagulating agents in the protein/hydrocolloid mixture of Shenouda by referring to column 3. lines 29-36 of Shenouda, where it says:

 The aqueous protein/alginate mixture is easily obtained by mixing the same in water. If necessary, the protein material can be finely divided or comminuted either before or after mixing with the water. The presence of soluble and/or insoluble non-coagulating materials is acceptable, and indeed in some cases desirable, so long as it does not adversely affect the desirable qualities of the fiber structure for a particular application. In some cases, the presence or addition of fat would modify the tensile properties of the

fibers. However, in other cases, a reduced tensile strength would be desirable as it would impart a more tender texture to the product. Thus, those additives normally employed in forming fibrous meat analog products can be employed according to the present invention; it being realized that the process of the present invention provides a process capable of widely modifying the compositional features of the fiber forming material to obtain a wide variety of textural and nutritional variations from the single basic process.

This passage contradicts the basis for the rejection. This passage of Shenouda effectively teaches that <u>additional</u> materials can be added to the aqueous protein/alginate mixture and that it is acceptable, and in some cases desirable, to <u>additionally</u> include soluble and/or insoluble non-coagulating materials.

The Examiner has incorrectly equated "non-coagulating" to "non-precipitating" (Answer, page 6, end of 3rd par.) and argued that since Monsanto teaches that sequestrant can be added to the hydrocolloid mixture before combining the hydrocolloid and protein so that the protein does not precipitate, it would have been obvious to employ such a sequestrant in the process taught by Shenouda.

As explained herein before, however, it is clear that the reference to non-coagulating materials in Shenouda relates to materials that can optionally be included in the alginate/protein mixtures of Shenouda, i.e. the term non-coagulating materials does not refer to protein or alginate. Indeed, it would contradict the teachings of Shenouda to reduce or avoid coagulation (precipitation) of protein and alginate as both components are purposely coagulated/precipitated in the production process taught by Shenouda. Furthermore, in the Shenouda process the alginate is precipitated by infusion with gelation ions and the protein is coagulated by heating.

Thus, whereas Monsanto teaches that protein precipitation can be avoided by using a sequestrant, there was no incentive for a person of ordinary skill in the art to take measures to

avoid protein precipitation in the process of Shenouda. Doing so would frustrate and render inoperable the intended objective of Shenouda of purposefully coagulating the protein. If a reference would be "rendered inoperable for its intended purpose, when it is modified for use as prior art, then the reference "teaches away" and should not be used." In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Hence, it would not have been obvious to add sequestrant to the protein/alginate mixture of Shenouda prior to the gelling by infusion with gelation ions.

In addition, Monsanto clearly teaches that protein precipitation only occurs at elevated temperatures (page 6, lines 33-34). Shenouda, to the contrary, teaches a process in which the protein is only subjected to elevated temperatures <u>after</u> the protein/alginate mixture has been thawed and gelled. What is more, these elevated temperatures are actually used to <u>coagulate</u> the protein. Hence, the use of a sequestrant before such heat treatment in order to avoid protein precipitation would go exactly against the teaching of Shenouda and frustrate Shenouda's objective.

"The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention." Application of Mercier, 515 F.2d 1161, 185 U.S.P.Q. 774, 778 (C.C.P.A. 1975). "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 353 F.2d 238, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965).

Thus the portions of Monsanto that conflict with and teach away from Shenouda cannot be ignored as in the Answer. Consideration of the full teachings of Shenouda and Monsanto shows there is no incentive to combine these references in the manner proposed in the Answer.

Contrary to the Answer it would not have been obvious to include a sequestrant with the hydrocolloid or the protein so that a stable product would be formed, as taught by Monsanto

To support the argument that it would have been obvious to include a sequestrant with the hydrocolloid or the protein so that a stable product would be formed, the Examiner has referred to page 3, lines 32-35; and page 6, lines 8-35 of Monsanto, where the following observations are made:

- Optionally, sequestrants such as sodium citrate1 at levels of up to 0.1% (e.g. between 0.01 - 0.1%) are used to facilitate gel formation and stability (page 3, lines 32- 35)
- The addition of calcium at high temperatures results in formation of undesirable protein precipitates as well as a gel which is not heat stable. (page 6, lines 26-28)
- These sequestrants reduce protein precipitation at elevated temperatures. (page 6, lines 34-35)

Clearly, what ensues from these observations in Monsanto is that sequestrants are needed to produce milk solids containing <u>heat-stable</u> (retort-stable) gellan gel pieces. This conclusion also finds support in the paragraph bridging pages 1 and 2 of Monsanto, where the problems associated with the use of milk solids in heat stable gellan gum pieces are described in detail:

• While gellan gum gel pieces formed with preselected ion types and concentrations have been prepared and are thermostable, gel pieces containing milk solids are difficult to form and generally not heat stable. Following procedures described in the prior art, where the source of calcium is added at or near the boiling point of the gellan gum solution, milk protein precipitates prior to formation of the gel. The resulting gel is a non-homogeneous melting gel which breaks down following exposure to retort conditions

(120°C for 20 minutes). Retort conditions are known in the art as those conditions used to sterilize foods.

As explained in the ensuing paragraph, Monsanto provides new gellan gum gel pieces containing milk solids which are retort-stable and solves the stability problem which arises when it is attempted to incorporate milk solids, including milk protein, in a gellan gum gel piece.

Monsanto's focus is on the retort stability of its gellan gum pieces. Monsanto makes no mention – whatsoever – of forming a fibrous product, let alone any problems associated with forming a fibrous product as a meat substitute.

The stability problems described in Monsanto are specifically related to the combined use of milk solids and gellan gum in the production of retort-stable gellan gum gel pieces. In contrast, Shenouda is concerned with alginate containing protein fiber bundles and does not deal with retort stability at all!

Thus the Examiner's proposed modification of Shenouda in view of Monsanto is unwarranted. "Modification unwarranted by the disclosure of a reference is improper." <u>Carl</u> Schenck, AG v Norton Corp., 713 F.2d 782, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983).

Since there is nothing in the record suggesting that the protein fiber bundles of Shenouda lack retort stability or even that it is relevant for such protein fiber bundles to be retort stable, and further since it is highly questionable whether the solution provided by Monsanto for gellan gum gel pieces would also be effective for alginate based protein fiber bundles, it can only be argued with the benefit of hindsight that Monsanto would have motivated a person of ordinary skill in the art to improve the stability of the protein fiber bundles of Shenouda by mixing alginate, protein and water in the presence of sequestrant, as recited in Applicant's claims. Hence, Monsanto would not have motivated a person of ordinary skill in the art to add sequestrant to the protein/alginate mixture of Shenouda prior to Shenouda's step of gelling by infusion with gelation ions.

As shown, there is no reason for the proposed combination Shenouda and Monsanto other than through hindsight. "Prior art may not be gathered with the claimed invention in mind."

Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 227, U.S.P.Q. 766, 768-9 (Fed. Cir. 1985). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). "(T)here must be some reason for the combination other than the hindsight gleaned from the invention itself." Interconnect Planning Corp. v. Feil. 774 F.2d 1132, 1143, 227 U.S.P.Q. 543 (Fed. Cir. 1985). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Dow Chemical, 837 F.2d 469, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Neither the suggestion, nor the expectation of success are found in the cited references herein.

Finally, it is noted that even if Monsanto would have motivated a person of ordinary skill in the art to modify the process taught by Shenouda by forming a homogeneous mixture of alginate, protein and water in the presence of sequestrant, this would not have led such person of ordinary skill to the method recited in the present claims. Shenouda fails to disclose a process that comprises mixing of the homogeneous mixture with a multivalent metal cation containing solution to form a fibrous product, recited for example in step (c) of claim 1. Instead, as explained herein before, Shenouda teaches a process that comprises infusing frozen fiber bundles with multivalent cations to reinforce the fiber-like structure in each bundle. Thus, even if Monsanto would have motivated a person of ordinary skill in the art to employ a sequestrant in the preparation of the fiber bundles according to the process taught by Shenouda, this would not have led such person to a method in which a fibrous product is formed by mixing a homogeneous mixture containing protein material, alginate, water and sequestrant with a solution of a multivalent metal cation.

It is well settled that "obviousness requires a suggestion of <u>all</u> limitations in a claim."

CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing In re Royka,

490 F.2d 981, 985 (CCPA 1974)) (emphasis added). At §2143.03, the MPEP requires the "consideration" of every claim feature in an obviousness determination. To render any claim unpatentable, however, the Office must do more than merely "consider" each and every feature of a claim. The asserted prior art must also teach or suggest each and every claim feature. See In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish prima facie obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art).

Accordingly, even if combined, the proposed combination of Shenouda and Monsanto would fail to meet each and every feature recited in Applicant's claims. The proposed combination thus further fails to render the claims obvious.

CONCLUSION

In view of the foregoing and the Arguments presented in the Appeal Brief, pending claims 1, 2, 4-14 and 21-27 are patentable over the applied cited prior art references and the rejection of these claims should be withdrawn. Applicant, therefore, respectfully requests that the Board of Appeals overturn the rejection of the pending claims and allow the claims.

Respectfully submitted,

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